seen why claim 14 should fall under this rejection.

The specification cites *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988) for its citation of eight factors used in determining whether undue experimentation is necessary to support the full scope of the claims. Those factors are:

(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Applicant submits that the most important point to consider with respect to *Wands* is that *Wands* does not prohibit all experimentation, only *undue* experimentation:

"Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. "The key word is 'undue,' not 'experimentation.'

"The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art. Ansul Co. v. Uniroyal, Inc. [448 F.2d 872, 878-79; 169 USPQ 759, 762-63 (2d Cir.1971), cert. denied, 404 U.S. 1018, 92 S.Ct. 680, 30 L.Ed.2d 666 (1972)]. The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed * * *."

With that in mind, Applicant takes issue with the analysis of the invention set forth in the Office Action.

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The prior art is correctly determined to be lubricants associated with and without prophylactic devices, and containing a spermicidal active. The Office Action alleges that the nature of the invention is "complex;" Applicant believes that the invention is relatively simple.

The combination of spermicide and lubricant goes back at least to 1971, disclosed for example in US 3,553,318. Numerous more recent patents exist. Such compositions do not act systemically, only topically, and it is relatively easy to determine if a particular composition is effective as a spermicide.

While the Office Action points out that the composition must be active against HIV and other viruses, Applicant notes that this must be topical effectiveness only, and moreover, antiseptic effectiveness. It is relatively easy to kill bacteria viruses on a surface, and easy to determine if such bacteria and viruses have been killed.

The Office Action states that the lack of predictability is high, and that an active agent effective in "preventing" the HIV virus may not be as effective against a more resistant strain "in a patient." More resistant *to what* is the operative question. The claimed compositions are not systemic antiviral agents to which to which resistant strains may develop; they are antiseptic agents capable of destroying a wide variety of microorganisms. The agents discussed in the present application have been found to be topically effective against HIV in general, without regard to strains.

In any event, given that only topical effectiveness is necessary, it is easy to determine if an antiseptic agent is effective; undue experimentation is not necessary.

The Office Action goes on the request that the specification should contain determinative evidence of the

rate of therapeutic success. "The level of predictability continues to face challenges in lie of the plethora of anti-HIV agents on the market for therapeutic use. The bioavailability comparison between an agent given by mouth in comparison to an agent applied topically also makes the level of unpredictability significantly high."

This requirement goes well beyond the invention. Applicant has not claimed a composition for curing HIV, nor is the present application an application for approval by the FDA. The present composition does not replace a composition to be taken by mouth, nor does it perform the same function as "the plethora of anti-HIV agents on the market." The Office Action has cited Applicant's own disclosure as suggesting a level of unpredictability; while there is always a level of unpredictability when considering the use of the prophylactics, there is certainly less unpredictability in the present field compared with systemic pharmaceuticals.

The Office Action further alleges that the specification does not provide adequate direction or guidance as to enablement of the instant invention in the prevention of HIV and other related viruses. It states that the specification discloses insufficient and/or fails to disclose pertinent studies drawn to the enablement of the prophylactic lubricant composition in the prevention of the HIV virus and other related viruses.

Once again, one must consider the actual purpose of the invention. As a set forth in the present specification, it is well known that spermicidally effective disinfectants and antiseptics destroy the natural flora of bacteria present in the area of the female genitals. With the destruction of that bacteria, there is a tendency for fungi to proliferate. Vaginal infections are known to result, along with a vaginal

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discharge, vulvar irritation, pruritis, external dysuria and unpleasant odors. See [0010]-[0011].

It is Applicant's discovery that the risk of infection can be reduced by reducing the risk of fungal infection. In order to accomplish this result, Applicant has proposed adding to a spermicidal lubricant composition in effect of the amount of a fungicide. This is exactly the guidance which has been provided to one of ordinary skill in the art that.

In order to determine if a composition is effective according to the invention, only three questions need be answered:

1) is a the composition's base a lubricant effective to reduce friction during sexual relations?

2) is the spermicidal antiseptic effect of both as a spermicide and as an antiseptic active against HIV and other viruses?

3) is the fungicide effective to prevent the growth of fungi in the vagina which grow in the absence of natural bacterial flora destroyed by the antiseptic?

Given the state of the art, it is not necessary to do extensive studies to select lubricants, spermicidal antiseptic, and fungicides. Materials effective for each of the above purposes are very well-known in the art, and indeed were cited in the prosecution of the parent application.

The Office Action alleges that "a determined quantity of experimentation" would be necessary to reasonably expect enablement. Applicant does not argue that *experimentation* would be necessary if one went beyond the bounds of the well-known materials for the cited purposes, but *undue experimentation* would not be necessary. As noted above, it is relatively easy to determine if the material is an effective lubricant, spermicide/antiseptic or fungicide. Extremely

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sophisticated testing is not required; indeed, such testing is discussed in the present specification. While Applicant has noted in the specification that it would not be ethical to perform testing in which humans would be expected to suffer ulceration (and even the less ethical to perform testing in which humans were exposed to the HIV virus), it is clearly a benefit in itself to provide a lubricant composition presenting a reduced risk of fungal infection.

The types of testing which are required to determine effectiveness of materials used according to the invention are relatively simple and would be expected to be fully reproducible and predictable. What is not predictable is how human beings will actually use such a composition in connection with sexual relations, but as with any such composition, results should be predictable when used as directed.

Applicant has pointed out that claims 13 and 15 have not been rejected on grounds of non-enablement. These claims apparently represent the compositions which have been specifically tested. Applicant further points out that replacements for each of the lubricant, antiseptic and fungicide in these compositions can easily be prepared and tested in the same manner that the compositions exemplified in the specification were prepared and tested. No undue experimentation is required; such testing is well known in the art and guidance is clearly provided in the present specification.

Withdrawal of this rejection is requested.

Claims 1-12 and 14 have been rejected under the judicially created doctrine of obviousness-type double patenting over claims 1 and 9 of US 6624198. Applicant recognizes the applicability of the double patenting

rejection, and will file a terminal disclaimer to remove this rejection at such time as the disputed claims are found to be allowable.

No claims have been rejected as unpatentable over prior art.

In view of the foregoing remarks, applicant submits that all claims are patentable. Favorable reconsideration is requested.

Respectfully submitted,

Ira J. Schultz
Registration No. 28666

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DENNISON, SCHULTZ & MACDONALD
SUITE 105
1727 KING STREET
ALEXANDRIA, VIRGINIA 22314-2700
703 837-9600